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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/602,840 | 06/23/2000 | Julie A. Kirihara | 950.011US2 | 1519 |

7590 05/21/2003
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EXAMINER

BAUM, STUART F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 05/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,840

Applicant(s)

KIRIHARA ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72,73,78,79,84,86,88-91 and 94-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72,73,78,79,84,86,88-91 and 94-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Appeal Brief submitted on 3/4/03 is acknowledged. Finality of the previous office action is withdrawn and a non-final office action is set forth.
2. Claims 72-73, 78-79, 84, 86, 88-91 and 94-110 are pending.
3. It was noted in Appendix A of the Amendment filed 6/19/2002 that Applicant canceled claimed 94. Because the notice to cancel claim 94 was stated in the Appendix and not in the body of the Amendment, claim 94 was not canceled. In the office action mailed 9/27/2002, Applicant was notified of the error regarding claim 94 but has since not acknowledged the notification. In addition, claim 94 does not appear in the list of claims accompanying the Appeal Brief. However, claim 94 is still pending.
4. Applicant is advised that future Appeal Briefs should not be bound as they have to be attached to the application and the plastic covers and spiral binders only add unnecessary bulk that makes it harder to attach to the application.
5. Claims 72-73, 78-79, 84, 86, 88-91 and 94-110 are examined in the present office action.

Specification

6. Applicant has not complied with conditions for receiving the benefit of an earlier filing date:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Applicant has only included a

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reference to application serial number 08/112245 and not to application serial number 08/763704.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 72-73, 78-79, 84, 86, 88-91, and 94-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 72, the recitation "augmented" has not been defined. Does Applicant mean that a nucleic acid sequence has been introduced into the genome of a maize plant? This is not an art recognized term and as such, it is not clear if the term incorporates other factors that have not been explicitly stated. All subsequent recitations of "augmented" are also rejected.

In claim 72, the metes and bounds of "preselected" have not been defined. It is unclear what is encompassed in a "preselected" DNA sequence. What constitutes a "preselected" DNA sequence? All subsequent recitations of "preselected" are also rejected.

In Claim 72, the metes and bounds of "substantially identical" have not been defined. What constitutes a substantial identity? Applicant has not defined the limits by which one skilled in the art would identify a DNA sequence as being "substantially identical". Would DNA sequences encoding beta- or gamma-zeins be encompassed by Applicant's claim to "substantially identical" sequences? All subsequent recitations of "substantially identical" are also rejected.

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In claim 88, the metes and bounds of "substantially complementary to all or a portion" have not been defined. Applicant has not defined the limits by which one skilled in the art would identify a DNA sequence as being "substantially complementary to all or a portion". Applicants recitation reads on one base pair. All subsequent recitations of "substantially complementary to all or a portion" are also rejected.

In claim 90, the metes and bounds of "substantially identical to all or a portion" have not been defined. Applicant has not defined the limits by which one skilled in the art would identify a DNA sequence as being "substantially identical to all or a portion". Would DNA sequences encoding beta- or gamma-zeins be encompassed by Applicant's claim to "substantially identical to all or a portion"? All subsequent recitations of "substantially identical to all or a portion" are also rejected.

In claim 94, the metes and bounds of "a gene which encodes kernel hardness" has not been defined. Applicants have not defined "kernel hardness" nor have they described genes which encode kernel hardness. This is not an art recognized term as genes encode protein not kernel hardness.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 72-73, 78-79, 84, 86, 88-91, and 94-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transgenic *Zea mays* plant having an increased starch content or an increased starch extractability comprising transforming a maize plant with a DNA sequence that is substantially identical or complementary to an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein, or comprising a DNA sequence that is substantially complementary or substantially identical to all or a portion of an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein; a method of producing a *Zea mays* seed with an increased starch content comprising transforming a maize plant with a DNA sequence that is substantially identical or complementary to an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein, or comprising transforming a maize plant with a DNA molecule that is substantially identical or substantially complementary to all or a portion of the mRNA sequence encoding any seed storage protein or encoding a 19 or 22 kD α -zein protein; or a transgenic *Zea mays* plant having an increased starch content or an increased starch extractability or a method of producing a *Zea mays* seed with an increased starch content, both plant and method comprising transforming a maize plant with a DNA sequence that is substantially identical or complementary to an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein and further transforming the plant with a DNA sequence encoding a polypeptide that provides the transgenic maize plant with increased kernel hardness.

The Applicants do not identify structural features unique to the maize 19 and 22 kD α -zein proteins that distinguish it from other storage proteins nor do they describe all the seed storage proteins that are claimed in claims 102 and 103, nor do they describe a DNA sequence

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encoding a polypeptide that provides increased kernel hardness. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of description for the maize 19 and 22 kD α -zein proteins, it remains unclear what features identify a maize 19 and 22 kD α -zein protein, including a sequence that is substantially complementary or substantially identical to all or a portion of a mRNA encoding a maize 19 and 22 kD α -zein protein. Given the broad claim language, Applicant's claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants from other plants and organisms, absent further guidance. Therefore, the written description requirement is not satisfied. Therefore, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111).

Enablement.

9. Claims 72-73, 78-79, 84, 86, 88-91, and 94-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a transgenic *Zea mays* plant having an increased starch content or an increased starch extractability comprising transforming a maize plant with a DNA sequence that is substantially identical or complementary to an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein, or comprising a DNA sequence that is substantially complementary or substantially identical to all or a portion of an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein; a method of producing a *Zea mays* seed with an increased starch content comprising transforming a maize plant with a DNA sequence that is substantially identical or complementary to an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein, or comprising transforming a maize plant with a DNA molecule that is substantially identical or substantially complementary to all or a portion of the mRNA sequence encoding any seed storage protein or encoding a 19 or 22 kD α -zein protein; or a transgenic *Zea mays* plant having an increased starch content or an increased starch extractability or a method of producing a *Zea mays* seed with an increased starch content, both plant and method comprising transforming a maize plant with a DNA sequence that is substantially identical or complementary to an mRNA molecule encoding a 19kD or 22kD α -zein seed storage protein and further transforming the plant with a DNA sequence encoding a polypeptide that provides the transgenic maize plant with increased kernel hardness.

The Applicants have not reduced to practice their claimed invention. The specification does not teach or provide guidance by way of disclosure or example how to increase the starch content of *Zea mays* plants or seeds, or produce seeds with kernel hardness. The specification only teaches how to make *Zea mays* seeds with a decreased amount of the amino acid leucine while increasing the amount of the amino acid lysine by transforming a *Zea mays* plant with the Z4 and A20 clones in antisense orientation (nucleic acid sequences encoding the maize 19 and 22 kD α -zein protein, SEQ ID NO's:1 and 2, respectively) (page 78, Table V and page 83, Table VI) operably linked to the Z10 promoter.

Furthermore, Coleman et al (1997, PNAS 94:7094-7097) teach that efforts to improve protein quality of maize seeds have focused on increasing the lysine content of the protein bodies within the endosperm. Two "high-lysine" mutants were identified, opaque2 (o2) and floury2 (fl2) which have a higher lysine content due to a reduction in the α -zein protein content of the endosperm. However, this reduction in α -zein protein content is concomitant with an inferior endosperm quality (page 7094, left column, 2nd paragraph). Therefore, based on Coleman et al, reducing the α -zein protein content of maize seeds using the strategy of the Applicants, will not increase the starch content of maize seeds.

Applicants have claimed *Zea mays* plants or seeds and a method, all of which comprise increasing the starch content by decreasing the amount of a seed storage protein presumably by antisense or co-suppression technology. The state-of-the-art teaches using sequences exhibiting below a 100% sequence identity as compared to a reference sequence produces unpredictable RNA degradation results. Moonan et al (2002, Journal of Virology 76(3):1339-1348) teach "sugarcane plants expressing untranslated viral capsid sequences of *Sorghum mosaic virus* strain

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SCH, challenged with SrMV viruses of strains SCM and SCI and *Sugarcane mosaic virus* strain, show various levels of virus resistance that correlated with the percentage of sequence identity of the transgenes to the sequence of the challenging virus" (page 1347, 1st paragraph, right column). Therefore, the protection achieved using sequences that exhibited less than 100% sequence identity to the respective viral gene resulted in an inferior viral protection.

Given the claim breadth, unpredictability and lack of guidance as stated above; given the breadth of the claims which encompass a multitude of sequences that have not been exemplified; it would require undue experimentation by one skilled in the art to identify and isolate a multitude of non-exemplified nucleic acid encoding sequences from a multitude of non-exemplified plants, and to evaluate the ability of these sequences or variants thereof to cause the claimed effects in maize transformed therewith.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

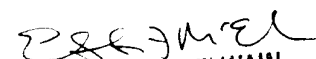
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

May 12, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1000